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ELI LILLY AND COMPANY

By

*KSRhoades*

Date

*2-5-04*

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	Mark Laurence Brader, <i>et al.</i>	)	Confirmation No.
			)	1579
Serial No.	:	10/600,031	)	
			)	Group Art Unit:
Filing Date	:	June 20, 2003	)	1654
			)	
For	:	Crystalline Compositions for Controlling	)	
		Blood Glucose	)	
			)	
Docket No.	:	X-14911A	)	

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provide a copy of each of the listed documents for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

Applicants request consideration of this information.

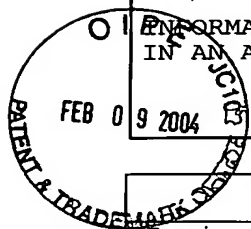
Respectfully submitted,

*Grant E. Reed*  
Grant E. Reed  
Attorney for Applicants  
Registration No. 41,264  
Phone: 317-276-1664

Eli Lilly and Company  
Patent Division/GER  
P.O. Box 6288  
Indianapolis, Indiana 46206-6288

*February 5, 2004*

FORM PTO 1449 (modified)	Atty. Docket No. X-14911A	Serial No 10/600,031
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicants Mark Laurence Brader, et al.	
	Filing Date June 20, 2003	Group 1654



## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pages or Relevant Figures Appear
	AA	US 2,538,018	08-04-1947	Krayenbuhl, et al.	
	AB	US 2,849,370	08-26-1958	Petersen, et al.	
	AC	US 3,868,358	02-25-1975	Jackson	
	AD	US 5,461,031	10-24-1995	DeFelippis	
	AE	US 5,547,930	08-20-1996	Balschmidt	
	AF	US 6,221,633	04-24-2001	Ertl, et al.	
	AG	US 6,268,335	07-31-2001	Brader	
	AH	US 6,465,426	10-15-2002	Brader	
	AI	US 6,531,448	03-11-2003	Brader	
	AJ	US 2002/0082199	06-27-2002	Brader	
	AK	US SN 10/338,101			

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Foreign Patent Document Country Code <sup>3</sup> -Number 4-Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	BA	WO 03/053460	07-03-2003	Brader, et al.		
	BB	EP 0 265 214	04-27-1988	Skelbaek-Pedersen		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FORM PTO 1449 (modified)	Atty. Docket No. X-14911A	Serial No 10/600,031
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicants Mark Laurence Brader, et al.	
	Filing Date June 20, 2003	Group 1654

CA	Pending Claims for US SN 10/010,038, Publication 2002/0082199	
CB	Pending claims for US SN 10/338,101	
CC	"Humulin® 70/30", Physician's Desk Reference, pp. 1592-1595, PDR/Medical Economics Co. (1999)	
CD	"Humulin® N," Physician's Desk Reference, pp. 1597-1600, PDR/Medical Economics Co. (1999)	
CE	"Humulin® U," Physician's Desk Reference, pp. 1605-1607, PDR/Medical Economics Co. (1999)	
CF	BALSCHMIDT, P., et al., "Structure of Porcine Insulin CocrySTALLIZED with Clupeine Z," <i>Acta Cryst.</i> (1991) B47, 975-986.	
CG	BENEDETTI, M., et al., "Kinetics and metabolic activity of biosynthetic NPH insulin evaluated by the glucose clamp technique", <i>Diabetes Care</i> , 7(2): 132-136 (1984).	
CH	BRADER, M., et al., "Hybrid insulin cocrySTALS for controlled release delivery," <i>Nature Biotechnology</i> 20:800-804 (2002)	
CI	BRANGE, J. et al., "Chemical stability of insulin. 2. Formation of higher molecular weight transformation products during storage of pharmaceutical preparations," <i>Pharmaceutical Research</i> , 9(6): 727-734 (1992)	
CJ	BRANGE, J., <i>Galenics of Insulin</i> , Springer-Verlag: New York, pp. 1-103 (1987).	
CK	BURKE, B., et al., "A comparison of the pharmacokinetics of human protamine sodium insulin with human isophane insulin following subcutaneous injection in normal subjects," <i>Diabetes Research</i> (1987) 4, 163-167.	
CL	COHEN, M., "Seaking a 'peakless' insulin: long-acting insulin analogues," <i>International Diabetes Monitor</i> 13(2):1-5 (2001).	
CM	COLWELL, A., "Nature and time action of modifications o protamine zinc insulin," <i>Archives of Internal Medicine</i> 74:331-345 (1944).	
CN	DEFELIPPIS, M., et al., "Preparation and characterization of a cocrySTALLINE suspension of [Lys <sup>B28</sup> , Pro <sup>B29</sup> ]-Human insulin analogue," <i>J. Pharm. Sci.</i> 87(2):170-176 (1998)	
CO	DODD, S., et al., "Reversible adsorption of soluble hexameric insulin onto the surface of insulin crystals cocrySTALLIZED with protamine: An electrostatic interaction," <i>Pharm. Res.</i> 12(1):60-68 (1995)	

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CP	FELIG, P., "Protamine insulin" <i>JAMA</i> , 251(3):393-396 (1984)	
CQ	FULLERTON, W., et al., "Insulin crystallization in the presence of basic proteins and peptides," <i>Biochi. Biophys. Acta</i> , 214:141-147 (1970).	
CP	HAGEDORN, H., et al., "Protamine Insulinate," <i>JAMA</i> , 106(3):177-180 (1936)	
CQ	KIM, Y., et al., "Precipitation of insulinotropin in the presence of protamine: effect of phenol and zinc on the isophane ratio and the insulinotropin concentration in the supernatant," <i>Pharm. Res.</i> , 12(9):1284-1288 (1995)	
CR	KRAYENBUHL, C. et al., "Crystalline protamine insulin," <i>Rep. Steno. Mem. Hosp. Nord. Insulinlab</i> , 1:60-73 (1946).	
CS	PRABHU S., et al., "A study of factors controlling dissolution kinetics of zinc complexed protein suspensions in various ionic species," <i>International Journal of Pharmaceutics</i> , 217:71-78 (2001)	
CT	ROOT, H., et al., "Clinical experience with protamine insulinate," <i>JAMA</i> , 106(3):180-183 (1936)	
CU	SCHLICHTKRULL, J., et al., "E. Insulin preparations with prolonged effect," In: <i>Handbook of Experimental Pharmacology, New Series</i> , vol. 32, pp. 729-777, Springer-Verlag, Hasselblatt, A. (Ed.) (1975)	
CV	SCOTT, D., et al., "Studies on insulin with protamine," <i>Journal Pharm. Exp. Therapeutics</i> , 58:78-92 (1936)	
CW	SIMKIN, R., et al., "Precipitation and crystallization of insulin in the presence of lysozyme and salmine," <i>Biochim. Biophys. Acta</i> , 200:385-394 (1970)	

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